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***Submitted via regulations.gov***

January 27, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS–9911–P

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 (CMS–9911–P)

Dear Administrator Brooks-LaSure:

On behalf of tens of millions of Americans who live every day with serious illnesses, including autoimmune diseases, the Autoimmune Association and additional undersigned organizations appreciate the opportunity to comment on the proposed rule titled *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023* (CMS–9911–P) (Proposed Rule), issued by the Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS or the agency).[1]

The Autoimmune Association is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity. Autoimmune diseases are a major cause of serious and chronic health conditions for millions of individuals. The Autoimmune Association is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 50 organizations representing numerous diseases, such as lupus, psoriasis, rheumatoid arthritis, multiple sclerosis, Sjögren's, celiac disease, relapsing polychondritis, and many others. The NCAPG's mission is to convene, support, and amplify the voice of autoimmune disease patients and patient groups to enhance capacity, collaboration, and impact through advocacy, education, awareness, and research concerning all aspects of autoimmune disease.

These comments focus on the following issues:

- **Serious, continued concerns about the current policy that permits issuers to exclude certain third-party assistance from patients' annual cost-sharing limitation.** We are disappointed that the Proposed Rule does not address this issue, and we strongly encourage CMS to ensure that all third-party copay and coinsurance assistance is counted toward patients' cost-sharing limits. Failing to do so significantly and unfairly impairs medication access and affordability for patients, creating barriers for those with chronic conditions to adhere to the therapy regimens prescribed by their physicians. These harmful consequences often result in negative health outcomes for patients and increased costs for our health care system. We urge CMS to address this important issue in the final rule.

- **Support for proposals addressing Affordable Care Act (ACA) nondiscrimination requirements**. These nondiscrimination protections are critically important for all individuals, and they play a vital

[1] 87 Fed. Reg. 584 (Jan. 5, 2022).

role in ensuring appropriate access to care for patients with autoimmune diseases and other serious and chronic conditions, given their unique and complex medical needs. We are committed to ensuring that the regulations and policies for implementing and enforcing the ACA's nondiscrimination requirements provide robust and consistent protections for patients, and we appreciate the Proposed Rule's attention to restoring, enhancing, and meaningfully enforcing these essential protections.

- **Support for proposals regarding network adequacy and standardized plan options**. We appreciate CMS's attention to these important policies and the proposals to strengthen network adequacy standards and to require standardized plan options beginning in plan year 2023 to help facilitate the plan selection process for consumers and to allow consumers to make more meaningful comparisons between plan offerings.

We address these points in further detail below, with particular focus on the needs and circumstances of individuals living with autoimmune diseases.

## I. Importance of Ensuring That Copay and Coinsurance Assistance Counts Toward Patients' Annual Cost-Sharing Limitation

We strongly urge CMS to revise existing regulations to require that any cost-sharing assistance provided to a patient by a third party to increase the accessibility and affordability of a prescribed medicine must be counted toward the patient's annual cost-sharing limitation. As CMS is aware, a regulatory provision added during the prior Administration—notwithstanding significant concerns raised by patient advocacy organizations and other stakeholders—states that issuers are not required to count toward the annual cost-sharing limitation "amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs."[2] Although the existing regulation permits issuers to count such assistance toward patients' annual cost-sharing limitation, it does not require them to do so. As a result, and to the detriment of patients, many issuers exclude this assistance from patients' annual cost-sharing limits.

As we have emphasized in prior comments, the policy permitting issuers to exclude this assistance from patients' annual cost-sharing limitations significantly harms patients, inappropriately hinders physicians' independent clinical treatment decisions, and unnecessarily impedes our important collective efforts to address the negative impact of chronic diseases across the country. At a time when policymakers should be focused on improving access to and affordability of prescription drugs for patients, this policy does the opposite.

Cost-sharing assistance from manufacturers, like other types of assistance, helps patients and their families cover their out-of-pocket costs for medicines, thereby facilitating the ability to maintain stability in their health conditions, avoid exacerbations or relapses, and achieve continuity of care. Those outcomes, in turn, reduce overall health care expenditures. Indeed, data and studies have shown that appropriate access to medications reduces, not raises, medical spending.[3] Permitting issuers to exclude this assistance from patients' annual cost-sharing limitations is unfair to patients, and it undermines CMS's important goals of improving access and affordability for patients.

Particularly for patients with serious and chronic conditions, including patients with autoimmune diseases, affordable access and continuity of care are imperative in order to manage their conditions, which often are

[2] 45 C.F.R. § 156.130(h).

[3] *See, e.g.*, Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012); J. Michael McWilliams et al., *Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage*, JAMA, 306(4):402–409 (2011) (finding that Medicare beneficiaries' increased access to and use of prescription drugs through expanded coverage under Part D was linked to reduced non-drug medical spending).

progressive, debilitating, or life-threatening, particularly in the absence of appropriate treatment. Accordingly, it is of paramount importance that patients with these conditions can obtain and maintain reliable access to the medically necessary therapies that their physicians prescribe.

Research has shown that, when patients face affordability challenges, increased out-of-pocket costs, or other barriers to accessing their prescribed medications, they are less likely to be able to adhere to their prescribed therapy regimens; prescription abandonment, therapy disruptions, discontinuations, and other issues are likely to occur.[4] Those obstacles to starting or continuing therapy have negative consequences for patients in terms of clinical outcomes,[5] which also leads to increased health care expenditures and other costs.[6] That, in turn, undermines cost-containment goals in light of the very high costs of hospitalizations and other clinical interventions and consequences that occur when patients' chronic conditions are not effectively managed.[7]

As advocates for people with autoimmune diseases and other chronic conditions, we understand the complexity and importance of this issue. Each patient requires highly individualized care, and effective treatments can take years of trial and error to identify. Physicians take great care in personalizing therapies and treatment plans for their patients, and the different available treatments are not interchangeable. Patients who are stable on a medication regimen depend on uninterrupted access to their prescribed therapies. Patients should not be penalized for using the resources available to them to assist with that access; it also seems arbitrary to penalize certain types of assistance but not others.

At a time when we should all be working to help patients with complex diseases to obtain and maintain access to the prescribed care and treatment that they need, we should avoid policies that impede—rather than improve—such access. Effective treatments greatly improve quality of life for millions of Americans, increase productivity, and assist in containing overall health care costs. Yet, many individuals living with serious and chronic conditions routinely face substantial financial challenges in managing their health. We believe that the policy permitting issuers to exclude certain assistance from patients' annual cost-sharing limitations imposes an unfair and unnecessary barrier to patients' ability to access, afford, and adhere to the treatment plans

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[4] *See, e.g.*, Patrick P. Gleason, *et al.*, *Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications*, Journal of Managed Care and Specialty Pharmacy (Oct. 2009); 15(8): 648–658; *available at* https://pubmed.ncbi.nlm.nih.gov/19803554/.

[5] *See, e.g.*, Jalpa A. Doshi, *et al.*, *Impact of Cost Sharing on Specialty Drug Utilization and Outcomes: A Review of the Evidence and Future Directions*, American Journal of Managed Care (Mar. 2016); 22(3): 188–197, *available at* https://pubmed.ncbi.nlm.nih.gov/27023024/#:~:text=CONCLUSIONS%3A%20Evidence%20to%20date%20generally,directions%20for%20research%20and%20policy; Teresa B. Gibson, *et al.*, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes*, American Journal of Managed Care (Aug. 2010); 16(8): 589–600, *available at* https://pubmed.ncbi.nlm.nih.gov/20712392/#:~:text=Results%3A%20A%20%2410%20increase%20in,OAD%20with%20or%20without%20insulin; Marie T. Brown & Jennifer K. Bussell, *Medication Adherence: WHO Cares?*, Mayo Clinic Proceedings, (April 2011); 86(4): 304–314, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/.

[6] *See, e.g.*, Stephan Kanzler et al., *Duration of Immunosuppressive Therapy in Autoimmune Hepatitis*, J. Hepatology, 34:354–355 (2001) (describing the importance of immunosuppressive therapy to sustained remission and prevention of relapse in patients with autoimmune hepatitis); Christopher C. Afendulis et al., *The Impact of Medicare Part D on Hospitalization Rates*, Health Servs. Res., 46(4):1022–38 (2011) (finding that implementation of Part D reduced hospitalization rates); Liisa Palmer, *et al.*, *Impact of Patient Cost Sharing on Multiple Sclerosis Treatment*, The American Journal of Pharmacy Benefits (2012) ("Suboptimal treatment adherence is common and associated with a higher risk of relapse, emergency department (ED) visits, hospitalizations, and medical costs."), *available at* https://www.pharmacytimes.com/publications/ajpb/2012/AJPB_2012_Nov/Impact-of-Patient-Cost-Sharing-on-Multiple-Sclerosis-Treatment.

[7] *See, e.g.*, Massachusetts Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 14 (noting, with citations to supportive studies, that "[r]esearch indicates that increasing medication adherence has the potential to reduce emergency department visits, hospitalizations, and overall health care costs for patients managing chronic conditions" and that "[p]rohibitive out-of-pocket drug costs are one factor contributing to poor medication adherence"); John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, NEJM, 354(22):2349–59 (2006) (finding that Medicare+Choice beneficiaries with a capped drug benefit had higher relative rates of ER visits, non-elective hospitalizations, and death, compared to those with unlimited drug coverage).

prescribed by their physicians. Addressing and removing this barrier is fully consistent with CMS's important goals to ensure appropriate access for patients, to "empower consumers," and to "improve affordability."[8]

For these reasons, we urge CMS to revise its current regulations and policies to ensure that all third-party copay and coinsurance assistance is counted toward patients' annual cost-sharing limitations.

## II. Support for Proposals to Restore, Enhance, and Meaningfully Enforce the ACA's Nondiscrimination Requirements

We support and applaud the Proposed Rule's attention to nondiscrimination requirements, including implementation of the nondiscrimination protections in ACA Section 1557, as well as the Essential Health Benefits (EHB) nondiscrimination requirements. These nondiscrimination protections are critically important for all individuals, and they play a vital role in ensuring appropriate access to care for patients with autoimmune diseases and other serious and chronic conditions, given their unique and complex medical needs.

For example, we support the proposals regarding the prohibition on discrimination in health care under ACA Section 1557 and regarding the regulations implementing EHB nondiscrimination protections, codified at 45 C.F.R. § 156.125. We appreciate the Proposed Rule's attention to health plan design issues, and we support the proposals for these regulatory provisions and policies that "are intended to ensure that benefit designs, and particular benefit limitations and plan coverage requirements are based on clinical evidence."[9]

We also support the Proposed Rule's inclusion of "examples that illustrate presumptively discriminatory practices that HHS believes amount to prohibited discrimination."[10] These examples are helpful in providing additional details and guidance for stakeholders in connection with these important protections, and can help ensure meaningful enforcement of these provisions. We also appreciate the Proposed Rule's express statement that it is providing "a ***non-exhaustive*** list of examples of presumptively discriminatory benefit designs" addressing certain issues that HHS/CMS "have seen most frequently."[11] We believe it is important to emphasize the "non-exhaustive" nature of these examples.

Issues of discrimination based on health conditions, as well as discrimination in connection with access to prescription drugs for chronic health conditions (including "adverse tiering"), are especially important for the autoimmune disease community. We appreciate and support the Proposed Rule's discussion of these issues in the context of nondiscrimination protections.[12] Autoimmune diseases include more than 100 different conditions that span a multitude of manifestations and uniquely affect each individual patient. Even within each disease state, patients with the same disorder experience varied symptoms and react differently to different treatments: what works for one lupus patient, or rheumatoid arthritis patient, or Sjögren's patient, for example, often will not work for another patient with the same disease.[13] This is further complicated by the

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[8] 87 Fed. Reg. at 585.
[9] 87 Fed. Reg. at 664.
[10] 87 Fed. Reg. at 664–668.
[11] 87 Fed. Reg. at 665 (emphasis added).
[12] 87 Fed. Reg. at 666–668.
[13] *See, e.g.*, Mayo Clinic, *Lupus: Symptoms & Causes* (Oct. 25, 2017), *available at* https://www.mayoclinic.org/diseases-conditions/lupus/symptoms-causes/syc-20365789 (last visited July 17, 2020) (noting that "[n]o two cases of lupus are exactly alike," and that "symptoms may come on suddenly or develop slowly, may be mild or severe, and may be temporary or permanent"); National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), *Health Topics: Rheumatoid Arthritis* (last reviewed Sept. 2019), *available at* https://www.niams.nih.gov/health-topics/rheumatoid-arthritis/advanced#tab-treatment (last visited July 17, 2020) (describing various treatments for rheumatoid arthritis and how they may vary from person to person, and noting that "[y]our doctor may recommend a combination of treatments, which may change over time based on your symptoms and the severity of your disease," and stating further that "[s]tudies show that early treatment with combinations of medications, instead of one medication alone, may be more effective in decreasing or preventing joint damage"); American College of Rheumatology, *Sjögren's Syndrome*,

fact that many autoimmune diseases have very few treatments available at all—and frequently do not have any generic equivalents or any available clinically appropriate substitutes that meet the patient's needs.

Even in cases where different therapy options potentially may exist for autoimmune disease patients, those options typically are not interchangeable for particular patients. Rather, patients' immune systems respond uniquely to different treatments. As a result, limited formularies, adverse tiering policies, and efforts to "steer" or "switch" patients to different medications that are or may appear to be lower in cost, but that are not necessarily clinically appropriate or optimal for the patient, can carry direct clinical risk. For example, abrupt loss of access to a therapy—particularly for patients with serious and chronic conditions that may be at risk for relapse—can threaten patients' long-term prognosis and recovery potential.[14] Similarly, patients with autoimmune diseases and other conditions may have immune sensitivities to active or inactive ingredients (such as dyes or fillers) in certain medications, such that being steered or switched to another (seemingly "lower cost") therapy, even if in the same category or class, may lead to adverse events, reduced efficacy, or other negative consequences.

For these reasons, it is essential for patients with autoimmune diseases to have access to the full range of medicines; this is critically important in light of these patients' individualized manifestations of autoimmunity and varied immune reactions and responses to different treatments. A number of patients with autoimmune diseases also have multiple autoimmune diseases and/or other conditions, thus adding further complexity to disease treatment and management.[15] As noted above, physicians take great care in personalizing therapies and treatment plans for their patients, taking into account the multiple factors and issues affecting each individual. Policies that impose barriers to accessing prescribed medicines create serious risks of harmful treatment delays and disruptions, and may result in failure to appropriately manage the myriad potential interactions among a patient's different medications and conditions.

We are committed to ensuring that the regulations and policies for implementing and enforcing the ACA's nondiscrimination requirements provide robust and consistent protections for patients, and we appreciate the Proposed Rule's attention to restoring, enhancing, and meaningfully enforcing these essential protections.

## III. Support for Proposals Regarding Network Adequacy and Standardized Plan Options

We support the Proposed Rule's efforts to "ensure that [qualified health plan (QHP)] enrollees would have sufficient access to providers" through certification requirements, network adequacy standards, and network adequacy reviews.[16] We agree with HHS's view "that strong network adequacy standards are necessary to achieve greater equity in health care and enhance consumer access to quality, affordable care through the Exchanges."[17] For autoimmune disease patients, the complexity of their conditions often requires care from multiple different specialists. As a result, narrow provider networks create particularly challenging circumstances for accessing and affording appropriate care. We appreciate CMS's proposed policies "to strengthen and clarify" existing network adequacy standards, "including expanding the provider specialty list

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*available at* https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Sjogrens-Syndrome (last visited July 17, 2020) (noting that "[s]ymptoms vary in type and intensity" and describing several types of treatments that may work in "some" patients but not others, depending on the patient's specific characteristics and symptoms).

[14] *See, e.g.*, David P. Richman & Mark A. Agius, *Treatment of Autoimmune Myasthenia Gravis*, Neurology, 61:1652–1661 (2003); Stephan Kanzler et al., *Duration of Immunosuppressive Therapy in Autoimmune Hepatitis*, J. Hepatology, 34:354–355 (2001).

[15] *See, e.g.*, NIH, *Progress in Autoimmune Diseases Research*, at i (Mar. 2005) (noting that "overlapping genetic traits enhance susceptibility to many of the diseases, so that a patient may suffer from more than one autoimmune disorder"); Mayo Clinic Staff, *Antidepressants: Another Weapon Against Chronic Pain* (Sept. 13, 2016), *available at* http://www.mayoclinic.org/pain-medications/art-20045647 ("[A]ntidepressants are a mainstay in the treatment of many chronic pain conditions, even when depression isn't recognized as a factor.").

[16] 87 Fed. Reg. at 680–685.

[17] 87 Fed. Reg. at 680.

for time and distance standards and adding appointment wait time standards."[18] We support CMS's ongoing efforts to ensure strong network adequacy standards, and we encourage CMS to consider additional policies to ensure appropriate access to specialists as it continues its important work in this area.

We also support the proposal to require issuers of QHPs to offer standardized plan options beginning in plan year 2023.[19] We appreciate the agency's thoughtful consideration of ways to facilitate the plan selection process for consumers and to allow consumers to make more meaningful comparisons between plan offerings.[20] If this proposal is finalized, we encourage CMS to carefully monitor its implementation to ensure that issuers comply with the requirements, and also to ensure that the requirements allow a sufficiently diverse range of plan options to meet consumers' unique health needs, as we understand CMS aims to do.[21]

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Thank you for your consideration of our comments. We look forward to continuing to work with you on these important issues.

Sincerely,

Molly Murray
President and Chief Executive Officer
Autoimmune Association

*On behalf of*:
Advocacy & Awareness for Immune Disorders Association (AAIDA)
Advocates for Responsible Care
American Behcet's Disease Association
APS Foundation of America, Inc.
Autoimmune Association
Beyond Celiac
California Chronic Care Policy Alliance
Color of Crohn's and Chronic Illness
Cystic Fibrosis Lifestyle Foundation
Cystic Fibrosis Research Institute
Foundation for Sarcoidosis Research
HealthyWomen!
International Cancer Advocacy Network
International Foundation for Autoimmune & Inflammatory Arthritis
International Pemphigus Pemphigoid Foundation
MCTD Foundation
National Alopecia Areata Foundation
Platelet Disorder Support Association
Prevent Blindness
Sjögren's Foundation
Whistleblowers of America

[18] 87 Fed. Reg. at 587.
[19] 87 Fed. Reg. at 587, 671–679.
[20] 87 Fed. Reg. at 673.
[21] 87 Fed. Reg. at 673.